



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,837	12/04/2003	Manne Satyanarayana Reddy	BULK 3.0-033	8513
45776 7590 03/25/2008 DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR, BRIDGEWATER, NJ 08807-2862				
EXAMINER				
COPPINS, JANET L				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
03/25/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/729,837

**Applicant(s)**

REDDY ET AL.

**Examiner**

JANET L. COPPINS

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 13-56 is/are pending in the application.
- 4a) Of the above claim(s) 17-32 and 35-56 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-9, 33 and 34 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-9 and 13-56 are currently pending in the instant application. Claims 17-32 and 35-56 are currently withdrawn from consideration as drawn to non-elected subject matter. Claims 1-9, 13-16, 33 and 34 were rejected in the previous Office Action.

***Response to Amendment***

2. Receipt is acknowledged of Applicants' Amendment and Response, filed December 6, 2007, which has been reviewed by the Examiner and entered of record in the file.

***Previous Claim Rejections - 35 USC § 112***

3. (a) Claim 2 previously rejected for incorporating a figure by reference. Applicants traverse the rejection, citing MPEP 2173.05 and arguing that the X-RDP for amorphous ziprasidone HCl cannot adequately be described, despite the Examiner's suggestions, and that "Applicants are truly unable to claims this subject matter in different way." The Examiner maintained in the previous rejection that the diffractometer provides the exact values for each peak based on a  $2\theta$  scale, and said values should be easily attainable by Applicants. The Examiner also previously noted that Applicants had neglected to label the y-axis of Figure 1 such that it is unclear what the  $2\theta$  values are measured against, e.g. intensity in counts per second.

The Examiner maintains the rejection to claim 2 and again recommends using language similar to the following, "The compound of claim 1, characterized by having significant X-ray powder diffraction pattern peaks expressed in  $2\theta$  values at ..." and then inserting specific peak values. The Examiner again reminds Applicants that Figure 1 must be corrected since neither the drawing nor the specification contains a label for the "y"-axis.

***Claim Rejections - 35 USC § 103***

4. Claims 1, 3-9, 13-16, 33 and 34 previously ejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,831,031 to Lowe, III et al, in view of U.S. Pat. No. 6,150,366 to Arenson et al, further in view of Lieberman, "Pharmaceutical Dosage Forms."

In view of Applicants' persuasive arguments, the Examiner withdraws the obviousness rejections of the claims.

***Conclusion***

5. Claims 1-9 and 13-56 are pending in the application. Claims 17-32 and 35-56 remain withdrawn from consideration, and claim 2 remains rejected.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins  
March 17, 2008

/Kamal A. Saeed/  
Primary Examiner, Art Unit 1626

